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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/215,077	12/18/1998	PAUL A. PRICE	2307O-086711	7823

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/215,077	Applicant(s) PRICE ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment filed 08 February 2002 has been received. Claims 1-8 are pending. Claims 9-17 have been canceled per the preliminary amendment filed on April 20, 2001.

Claim Rejections - 35 USC § 112

2. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph for reasons of record in the previous office action.

Specifically, the specification, while being enabling for screening the presence of alcoholic cirrhosis of the liver which is associated with degradation of connective tissue containing YKL-40 in a patient suspected of having alcoholic cirrhosis of the liver, does not reasonably provide enablement for a method of screening for a cirrhosis of the liver in any and all mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because according to Applicant, YKL-40 is used in combination with a number of other indicators to make a differential diagnosis of cirrhosis of the liver. However, it is unclear what "other indicators" may be used to make a differential diagnosis since these other indicators are not clearly state in the claims. Further, the claim is confusing because it is not a claim directed to a "differential diagnosis" of cirrhosis of the liver, but is apparent from Applicant's argument that this is how the claim should be interpreted.

Double Patenting

4. The rejection of claims 1-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of US 5,935,798 is hereby withdrawn in view of the amendment to the claims.

Response to Arguments

5. Applicant's arguments filed February 8, 2002 have been fully considered but they are not persuasive.

Applicant argues that the claims are fully enabled because even where there is no suspicion of cirrhosis of the liver, in light of the teaching provided in the specification, an elevated YKL-40 level will lead one of skill to consider the possibility that the assayed mammal does suffer from cirrhosis of the liver.

This argument has been fully considered but is not deemed to be persuasive. According to the specification, an elevated level of YKL-40 may be related to several diseased conditions, specifically, breast cancer, joint diseases including rheumatoid arthritis and osteoarthritis. Therefore, when there is no suspicion of cirrhosis of the liver, an elevated YKL-40 level does not lead one directly to the possibility of cirrhosis of the liver. Instead, it may lead one to consider a host of other diseased conditions that may be associated with elevated YKL-40, resulting in undue experimentation to practice the claimed invention.

Applicant argues that an elevated YKL-40 level will lead one of skill in the art to consider that the subject mammal has cirrhosis of the liver; elevated YKL-40 is, therefore, an indicator of cirrhosis. Applicant argues that like other assays for a disease state, the claimed assays are performed in the context of a differential diagnosis. Applicant also argues that the

amended claims provide an indicator of cirrhosis and conformation of the disease state is routine to those in the medical profession.

These arguments have been fully considered but are not deemed to be persuasive. As stated above, the specification does not provide enough information for one skill in the art to diagnose cirrhosis of the liver in any and all mammals, including those not suspected of having cirrhosis of the liver from an elevation in YKL-40 level. The specification teaches that elevated YKL-40 levels are associated with a number of different diseases, thus, without further specific guidance for how skill in the art may narrow the diagnosis, it would require undue experimentation to make and use the invention as claimed.

The argument that like other assays, the claimed assays are performed in the context of a differential diagnosis has been fully considered but is not deemed to be persuasive. The claim does not make clear that the assay is performed in the context of a differential diagnosis. Further, the argument that the claim provides an indicator of cirrhosis has been fully considered but is not persuasive because no other indicators are taught nor claimed. Therefore, it is unclear how YKL-40 may be used along with any other indicators to diagnose cirrhosis of the liver.

Applicant argues that enablement does not require that the claimed assay provide a completely unambiguous determination of the presence of cirrhosis. To the contrary, all assays provide a certain incidence, e.g. of false positives, and that the instantly claimed assay is similar. Therefore, applicant argues that the claimed invention is thus commensurate in scope with the disclosure and the examples provided therein, and no undue experimentation is required to practice the claimed invention.

This has been fully considered but is not deemed to be persuasive. 35 U.S.C. 112, first paragraph requires that

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

While it may be true that 112, first paragraph does not specifically requires that the claimed invention provides a completely unambiguous determination, it does require that the claimed invention be enabled. In the instant case, something with the scope of the claim is enabled but the claims are not limited to that scope as explained in the prior office action and in the response above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
April 10, 2002